DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on New Approach Methodologies for Efficacy Testing of Ectoparasiticide Products to Meet Regulatory Data Requirements

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for efficacy testing of ectoparasiticide products. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the efficacy of ectoparasiticides on dogs and cats and to facilitate their incorporation into a testing strategy for regulatory purposes.

DATES: Receipt of information: Deadline for receipt of information is January 28, 2022.

ADDRESSES: Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM; email: nicole.kleinstreuer@nih.gov; telephone: (984) 287-3150.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use. As part of this activity, NICEATM supports efforts to develop, validate, and implement alternative approaches for chemicals and medical products. These include approaches used to evaluate the efficacy of ectoparasiticides on dogs and cats, such as products to prevent flea and tick infestations. Tests on such

products are required by multiple federal agencies for regulatory and other decision contexts. Currently, the standard tests for this endpoint use animals that can experience significant discomfort and distress during the study.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to predict the efficacy of ectoparasiticides without using animals. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo test methods currently used by federal agencies for regulatory and other decision contexts.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is January 28, 2022. Responses to this notice will be posted at: https://ntp.niehs.nih.gov/go/niceatm-data. Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides

authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods. Information about NICEATM and ICCVAM can be found at https://ntp.niehs.nih.gov/go/niceatm and https://ntp.niehs.nih.gov/go/iccvam.

Dated: December 13, 2021.

Brian R. Berridge,

Associate Director,

National Toxicology Program.

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